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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/817,652

04/02/2004

Charles Frederick Lloyd

144382NV (15427US01)

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EXAMINER

WEATHERBY, ELLSWORTH

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

06/26/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/817,652	Applicant(s) LLOYD ET AL.	
	Examiner ELLSWORTH WEATHERBY	Art Unit 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-9 and 12-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6-9 and 12-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-4, 6-9, and 12-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 5-10, 13-16, and 19-21 of copending Application No. 10/962019. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application involve an obvious broadening of the claims in the co-pending application. Also, changing between implant and instrument would have been obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-4, 6-9, and 12-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Seeley et al. (USPN 6,490,475).

5. Seeley et al. teaches a system for improved calibration of an instrument, said system comprising: an instrument for use in an image-guided operation, said instrument tracked with respect to a reference coordinate system during said image-guided operation (abstract); a plurality of fiducials placed on said instrument, said plurality of fiducials enabling measurement of said instrument (col. 5, l. 55- col. 6, l. 8); a sensor for measuring said instrument, said sensor capable of being positioned with respect to one or more of said fiducials for measurement of one or more locations on said instrument (col. 6, ll. 9-41); and a tracking system for measuring one or more locations on said instrument using said sensor and said plurality of fiducials in closed form registration to calibrate said instrument, wherein said tracking system compares measurements from said instrument with a model for said instrument to determine a variation based on

deformity of the instrument (abstract; col. 4, ll. 26-30), said tracking system adjusting tracking of said instrument based on said variation (abstract; col. 4, l. 47-col. 5, l. 7), wherein said tracking system further comprises a feedback mechanism used during surgical navigation to determine accuracy of tracking of the instrument by comparing tracked versus actual instrument position to determine whether positional accuracy is within a certain tolerance and recalibrating the instrument during surgical navigation if the positional accuracy is outside the certain tolerance (col. 6, ll. 9-42; col. 9, ll. 4-25). Seeley further teaches using geometrical fiducials (col. 5, ll. 32-54). Seeley et al. also teaches comparing measurements to a model (abstract; col. 5, ll. 7-31).

Response to Arguments

6. Applicant's arguments filed 2/01/2008 have been fully considered but they are not persuasive.

7. Applicant alleges that Seeley does not suggest “wherein the tracking system further comprises a **feedback mechanism used during surgical navigation** to determine accuracy of tracking the instrument by **comparing tracked versus actual instrument position** to determine whether positional accuracy is within a **certain tolerance** and **recalibrating the instrument during surgical navigation if the positional accuracy is outside the certain tolerance.**” The examiner will explain below that Seeley teaches Applicant's cited deficiencies.

8. To clarify the Examiner's interpretation of the Seeley in teaching the above alleged deficiencies, the Examiner refers to the current specification: "A feedback mechanism is used during surgical navigation to determine accuracy of tracking of an instrument. Comparison of tracked versus actual instrument position may be quickly checked during a procedure. If positional accuracy is within acceptable limits, then the procedure may continue with the instrument. If positional accuracy is outside an acceptable tolerance or if the instrument is incapable of tracking due to a deformity, then the instrument may be recalibrated quickly during the procedure. Then the instrument may continue to be used in the procedure."

9. Seeley teaches improving instrument tracking accuracy at column 13, l. 54-col.14, l. 56, which anticipates Applicant's claimed feedback process. Here, Seeley teaches tool navigation, where tracking system T1 tracks the tool's *actual position* (col. 14, ll. 34-36). A processor forms a model of the tool in an image and determines its *tracked position* (in "fluoroscope image space") by applying the camera calibration matrix to the tool's actual position such that the image of the tool is dynamically calibrated to "fluoroscope image space" (col. 14, ll. 36-38). That is, Seeley teaches defining an absolute position of an image plane for a plurality of planes to identify a reference coordinate system (col. 14, ll. 38-42). This allows the *actual position*, which is defined by tracking system T1, of the tool to be converted to a *tracked position*, which is in the absolute or reference image plane (col. 14, ll. 40-42). In short, the *actual position* compared to the *tracked position* allows one to scale and correct positions of the tool

model in the image (col. 9, ll. 25-48; col. 14, ll. 52-56). This is a dynamic calibration procedure, as described below.

10. The scaling and correction is applied during an ongoing tracking procedure, where a tracking assembly tracks tool movement relative to the patient, and a processor controls the tracking and determines when it is necessary to redraw the integrated display using the above-described image transformations to correctly situate the displayed tool in a position on a new image (col. 14, ll. 26-33).

11. Thus, in the above discussion, Seeley expressly shows a **feedback mechanism** that uses both **an instrument's actual position** relative to **(or compared to)** that instrument's **tracked position** in an image, where by **comparing the actual position to the tracked position** a processor determines when it is necessary to redraw (and recalibrate) the integrated image to achieve a **certain accuracy** such that the position of the instrument model is correctly displayed in each new integrated image (col. 14, ll. 26-33; col. 16, ll. 3-15).

12. As noted in the 1/10/2008 the processor computes the calibration as well as geometric distortion due to the imaging process, and *converts the tracked or actual location of the tool to a distorted tool image position* at which the display projects a representation of the tool onto the fluoroscopic image to guide the surgeon in tool navigation (col. 4, l. 61- col. 5, l. 7). The examiner stood in the 1/10/2008 Non-Final Rejection that the above described calibration processing satisfied the claim limitation "wherein the tracking system further comprises a **feedback mechanism used during surgical navigation** to determine accuracy of tracking the instrument by **comparing**

tracked versus actual instrument position to determine whether positional accuracy is within a **certain tolerance** and **recalibrating the instrument during surgical navigation if the positional accuracy is outside the certain tolerance.**" Accordingly *and because Applicant has presented no further arguments* with respect the 102(e) rejection of Claims 1-4, 6-9 and 12-20, the 102(e) rejection of Claims 1-4, 6-9 and 12-20 stands Final.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLSWORTH WEATHERBY whose telephone number is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/
Primary Examiner, Art Unit 3737

EW